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10/510,628

05/09/2005

Peter Hegemann

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EXAMINER

BALLARD, KIMBERLY

ART UNIT

PAPER NUMBER

1649

NOTIFICATION DATE

DELIVERY MODE

11/09/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/510,628 | <b>Applicant(s)</b><br>HEGEMANN ET AL. |  |
|                              | <b>Examiner</b><br>Kimberly Ballard  | <b>Art Unit</b><br>1649                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 9, 13-26 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 19-26, 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. Claims 1, 3, 9 and 35 have been amended, claims 8 and 10-12 have been canceled, and new claims 36-38 have been added as requested in the amendment filed July 21, 2009. Following the amendment, claims 1-5, 9, 13-26 and 32-38 are pending in the present application.
2. Claims 13-18 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in the response filed on November 1, 2007.
3. Accordingly, claims **1-5, 9, 19-26**, and **32-38** are under examination in the current office action.

### ***Withdrawn Claim Rejections***

4. Any rejection or objection of record of claim 10 is rendered moot in view of Applicants' cancellation of the claim.
5. The rejection of claim 9 under 35 U.S.C. 112, first paragraph (written description and enablement), set forth at paragraphs 8-10 of the previous office action (mailed 03/23/2009), is withdrawn in view of Applicants' amendment to the claim.

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6. The rejection of claims 1-4, 19-22, 24-26, 33 and 35 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 7,144,733 B2 to Miesenböck et al., set forth at paragraph 12 of the previous office action mailed 03/23/2009, is withdrawn in view of Applicants' amendments to the claims.

7. The rejection of claims 1-4, 19, 21-26, and 32-35 under 35 U.S.C. 102(b) as being anticipated by Abdulaev and Ridge (*Methods Enzymology*, 2000; 315:3-11), set forth at paragraph 13 of the previous office action mailed 03/23/2009, is withdrawn in view of Applicants' amendments to the claims.

8. The rejection of claims 1-5, 19, 21-22, 24-26, 33 and 35 under 35 U.S.C. 102(b) as being anticipated by Han et al. (*Biochemistry*, 1998; 37: 8253-8261), set forth at paragraph 14 of the previous office action mailed 03/23/2009, is withdrawn in view of Applicants' amendments to the claims.

***New Claim Rejections and Objections, Necessitated by Amendment***

***Claim Rejections - 35 USC § 112, first paragraph***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5, 9, 19-26 and 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are directed to a method for increasing or decreasing the ion conductivity of a membrane, comprising inserting one or more directly light-controlled ion channels into a membrane, wherein the one or more directly light-controlled ion channels is a biological photoreceptor which comprises an apoprotein and a light-sensitive polyene covalently bound to the apoprotein, said polyene interacting with the apoprotein and functioning as a direct light-sensitive gate, thereby increasing or decreasing the ion conductivity of the membrane. Thus, the claims are drawn to a method of using a genus of directly light-controlled ion channels, and are therefore considered genus claims.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Applicants are directed to the recently-published guidelines on interpretation of the written description requirement, available on the internet at: <http://www.uspto.gov/web/menu/written.pdf>. In this case, the only factor present in the claims is the functional characteristic of the ion channel (capable of direct light-controlled ion transport). The claims also recite that the polyene

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interacting with the apoprotein functions as a direct light-sensitive gate, but there are no explicit structural requirements for the apoprotein present in claims, and the specification teaches only that an apoprotein is a membrane protein with at least 5 transmembrane helices and is capable of binding a light-sensitive polyene (page 3). The specification discloses two specific apoproteins derived from the motile green algae *Chlamydomonas reinhardtii*, Channelopsin1 (CHOP-1; SEQ ID NO: 1) and Channelopsin2 (CHOP-2; SEQ ID NO: 2), which are identified as directly light-controlled passive ion transport proteins. The specification also notes that "structurally and/or functionally similar rhodopsin proteins also occur in other microalgae and in gametes and zoospores of macroalgae and possibly in other organisms" (p. 8, 3rd paragraph), but cites no specific examples of these. Further, the specification discloses that apoproteins from green algae other than *Chlamydomonas reinhardtii*, as well as apoproteins from protozoa, bacteria, archaeobacteria, and fungi (see p. 7) may also be used in the invention, but makes no indication as to whether these other apoproteins possess the desired directly light-controlled ion transport function. Apoproteins comprising certain structural consensus motifs, such as LDxxxKxxW (SEQ ID NO: 6) are also disclosed, but this consensus motif is noted to define the retinal binding site of apoprotein molecules and not necessarily the sequence which allows for direct light-controlled ion channel transport. This is evidenced by the fact that this consensus sequence is found in other bacteriorhodopsins (see p. 8) which presumably transport ions through indirect light-controlled channels (as argued in the response filed July 21,

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2009). Moreover, the art is silent with respect to the identity of other such direct light-controlled ion channel transport proteins.

Therefore, the limited examples of CHOP-1 and CHOP-2 from *Chlamydomonas reinhardtii* do not provide sufficient evidence of the broad genus of directly light-controlled ion channels instantly claimed, especially since it is not known whether any other such apoproteins from *C. reinhardtii* or from other organisms possess such apoproteins that would be consistent with use within the claimed method. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of the apoproteins CHOP-1 and CHOP-2 from *Chlamydomonas reinhardtii*, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The

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compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only methods comprising the use of the apoproteins CHOP-1 (SEQ ID NO: 1) or CHOP-2 (SEQ ID NO: 2) from *Chlamydomonas reinhardtii*, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

11. Claims 1-5, 9, 19-26 and 32-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for increasing or decreasing the ion conductivity of a membrane comprising inserting one or more directly light-controlled ion channels into a membrane, wherein the one or more directly light-controlled ion channels is a biological photoreceptor and comprises an apoprotein and a light-sensitive polyene covalently bound to the apoprotein, said polyene interacting with the apoprotein and functioning as a direct light-sensitive gate, and wherein the apoprotein comprises at least amino acids 61 to 310 of the Channelopsin1 (CHOP-1) protein (SEQ ID NO: 1) or at least amino acids 24 to 268 of the



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Channelopsin2 (CHOP-2) protein (SEQ ID NO: 2), does not reasonably provide enablement for the claimed method comprising the use of any directly light-controlled ion channel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The claims are directed to a method for increasing or decreasing the ion conductivity of a membrane, comprising inserting one or more directly light-controlled ion channels into a membrane, wherein the one or more directly light-controlled ion channels is a biological photoreceptor which comprises an apoprotein and a light-sensitive polyene covalently bound to the apoprotein, said polyene interacting with the apoprotein and functioning as a direct light-sensitive gate, thereby increasing or decreasing the ion conductivity of the membrane.

In general, the claims require the use of a broad genus of directly light-controlled ion channel molecules and as stated above, Applicants have not described all of the common features of the genus such that the skilled artisan could identify individual members. Applicants have not provided sufficient guidance, for example by showing a

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correlation between unique structural characteristics and the desired functional effect, to allow one of skill in the art to practice the claimed invention with any directly light-controlled ion channel, which meets the limitations of the claims. The working examples are directed exclusively to the use of CHOP-1 and CHOP-2 proteins. As stated previously, these limited examples do not provide sufficient disclosure such that one of skill in the art would conclude that Applicant was enabled for the structural attributes of a representative number of species possessed by the genus of direct light-controlled ion channel proteins encompassed by the claimed invention.

Again as noted above, the state of the art is silent with respect to the precise identity of other directly light-controlled ion channel transporters besides the CHOP-1 protein. For example, Nagel et al. (*Science*, 2002 Jun; 296:23995-2398; of record) teaches Channelrhodopsin-1 (ChR1), which comprises the CHOP-1 apoprotein, and hypothesizes that other such directly light-sensitive ion channels may exist in other microalgae, as well as in gametes and zoospores of macroalgae, or even in fungi (see p. 2397, last paragraph). The prior art does not, however, actually identify any such ion channels or propose identifying structural features of such directly light-sensitive channels.

The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly,

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extensive and undue. See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. Due to the large quantity of experimentation necessary to determine which of the claimed plurality of directly light-controlled ion channels encompassed by the claims would be capable of achieving the desired functional effect, the limited working examples directed to same, the state of the prior art which illustrates the unpredictability of the determining and using such channels, and the breadth of the claims, undue experimentation would be required of the skilled artisan to make and use the invention commensurate in scope with the claimed method.

### ***Double Patenting***

12. Applicant is advised that should claim 9 be found allowable, claim 37 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Conclusion***

13. Claims 1-5, 9, 19-26 and 32-37, as amended, are rejected. Claim 38 is allowable.

14. This application contains claims 16-18 drawn to an invention nonelected with traverse in the reply filed on November 1, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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